

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

DRUGS FOR HUMAN USE

3386. Misbranding of pentobarbital sodium capsules. U. S. v. Bunting & Son, Inc. Plea of guilty. Fine, \$800. (F. D. C. No. 29460. Sample Nos. 2936-K to 2939-K, incl.)

INFORMATION FILED: October 17, 1950, Eastern District of Tennessee, against Bunting & Son, Inc., Bristol, Tenn.

INTERSTATE SHIPMENT: From the States of Ohio and Illinois into the State of Tennessee, of quantities of *pentobarbital sodium capsules*.

ALLEGED VIOLATION: On or about August 8, 11, 15, and 22, 1949, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repackaged and sold without a prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use, in that the directions "One capsule at bedtime as needed for rest," borne on the labeling, were not adequate directions for use.

DISPOSITION: March 5, 1951. A plea of guilty having been entered, the court imposed a fine of \$800 against the defendant.

3387. Misbranding of phenobarbital tablets. U. S. v. Nicholas Paris (Paris Drug Store). Plea of nolo contendere. Defendant fined \$500 and placed on probation for 1 year. (F. D. C. No. 29993. Sample Nos. 49741-K, 49743-K, 75194-K.)

INFORMATION FILED: December 20, 1950, District of Colorado, against Nicholas Paris, trading as the Paris Drug Store, Denver, Colo.

INTERSTATE SHIPMENT: On or about February 28, 1950, from the State of Missouri into the State of Colorado, of a quantity of *phenobarbital tablets*.

ALLEGED VIOLATION: On or about April 3, 6, and 10, 1950, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the tablets to be repackaged and sold without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged *phenobarbital tablets* failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the tablets contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative

and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the directions, namely, "One tablet three times a day fifteen minutes before meals and at bedtime" and other similar directions borne on the labeling were not adequate directions for use.

DISPOSITION: March 7, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$500 against the defendant and placed him on probation for 1 year.

3388. Misbranding of male hormone tablets. U. S. v. Marvin Nashkin (Gold Seal Pharmacal Co.). Plea of guilty. Fine of \$250, plus costs. (F. D. C. No. 29432. Sample No. 57056-K.)

INFORMATION FILED: June 28, 1950, Northern District of Ohio, against Marvin Nashkin, trading as the Gold Seal Pharmacal Co., Cleveland, Ohio.

ALLEGED SHIPMENT: On or about November 28, 1949, from the State of Ohio into the State of New Jersey.

LABEL, IN PART: "Male Hormone (Methyl Testosterone) Regular Directions For use by adult males mildly deficient in male hormones when small dosages of male hormones are prescribed or recommended by a physician for palliative relief of such symptoms. Daily recommended intake of one light tablet provides 5 mg. of Methyl Testosterone in specially prepared base for sublingual use. Suggested Dosage One light tablet upon arising before breakfast. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from 3 to 6 months, under supervision of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying leaflet entitled "Attention! Men! Hormones" were false and misleading. The statements represented and suggested that the article would be of value to adult males mildly deficient in male hormones; that it would be of value to men beginning to feel past their prime; that it would constitute an adequate and effective treatment for diminished energy and vitality, worry over general health, depressed feeling, fatigue, irritability, excessive nervousness, and other common symptoms of the male climacteric; and that it would be efficacious in bringing men happiness and a longer useful life. The article would not accomplish the purposes claimed, and it would not constitute an adequate and effective treatment for the conditions so represented and suggested.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions, in that the directions for use borne on the labeling of the article were not adequate directions for use.

DISPOSITION: February 23, 1951. A plea of guilty having been entered, the court imposed a fine of \$250, plus costs, against the defendant.